UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

ID

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/121,211	07/23/98	SHINOHARA	B0801/7116

HM22/1120

EDWARD R. GATES
WOLF, GREENFIELD & SACKS
600 ATLANTIC AVENUE
BOSTON MA 02210

EXAMINER	
ROMEO, D	

ART UNIT	PAPER NUMBER
1647	15

DATE MAILED: 11/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/121,211	Shinohara et al.
Examiner	**Group Art Unit**
David Romeo	1647

☒ Responsive to communication(s) filed on *5 Sep 2000*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-22, 26, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, and 70* is/are pending in the application.

Of the above, claim(s) *12-22, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, 70* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 4-11, and 26* is/are rejected.

☒ Claim(s) *2 and 3* is/are objected to.

☒ Claims *1-22, 26, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, 70* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

2. The amendment filed 09/05/00 (Paper No. 14) has been entered. Claims 1-22, 26, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, 70 are pending. Claims 12-22, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, 70 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 9. Claims 1-11, 26 are being examined. Claim 26 is being examined only to the extent that it reads upon an agent that is a nucleic acid molecule.

3. Amended claim 26 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention originally claimed is drawn to a nucleic acid molecule classified in class 435, subclass 69.1. Amended claim 26 is drawn to or encompasses a polypeptide classified in class 530, subclass indeterminable. The products are independent and distinct, wherein neither is required for the production or use of the other, and wherein each can be manufactured independently of the other and used for independent and distinct purposes.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 26 is withdrawn from consideration to the extent that it is directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 8, 10, 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' arguments have been fully considered but they are not persuasive.

The decision in Fiers relied upon the decision in Amgen for establishing conception of the claimed invention. In the instant case, the specification discloses a single human sequence encoding a protein with the desired activity. The claims are directed to or encompass all nucleic acid molecules that hybridize to SEQ ID NO: 1 and encode a protein with the desired activity. There is no description of such hybridizing nucleic acid molecules or of the proteins they encode

having the desired activity. With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and therefore conception is achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

The decision in Fiddes is applicable to the instant claims because the claims are directed to or encompass a broad class of nucleic acid molecules that hybridize to SEQ ID NO:1 and encode a polypeptide, which corresponds to nucleic acid molecules from other species, mutated nucleic acid molecules, allelic variants, splice variants, and nucleic acid molecules having some degree of identity, similarity, or homology, whereas the instant specification, like the situation in Fiddes, only provides a single species' sequence, specifically the human sequence.

In addition to holding that "[i]n claims to genetic material, generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not adequate written description of claimed genus", the court in Lilly also held that "Patent specification does not provide adequate written description of claimed microorganism containing human insulin-encoding cDNA, since patent includes example providing process for obtaining human insulin-encoding cDNA, and describes protein that cDNA encodes, but provides no further information, such as sequence information indicating which nucleotides constitute human cDNA, pertaining to that cDNA's relevant structure or physical characteristics. The court in Lilly also held that "Patent's description of amino acid sequence of human insulin A and B chains fails to

provide adequate written description of claimed microorganism containing human insulin-encoding cDNA, since description which renders claimed invention obvious is not sufficient to satisfy written description requirement of that invention, since claim to specific DNA is not made obvious by mere knowledge of desired protein sequence and methods for generating DNA that encodes that protein, and since description that does not render claimed invention obvious therefore does not sufficiently describe that invention for purposes of 35 USC 112." In the instant case, the specification discloses a single human sequence encoding a protein with the desired activity. The claims are directed to or encompass all nucleic acid molecules that hybridize to SEQ ID NO: 1 and encode a protein with the desired activity. There is no description of such hybridizing nucleic acid molecules or of the proteins they encode having the desired activity. With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and therefore conception is achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Whereas the instant specification provides a detailed description of a particular DNA molecule, SEQ ID NO:1, encoding a particular protein, SEQ ID NO:2, the instant specification does not provide a structural formula which is definitive of all hybridizing DNA molecules and mutated variants thereof that encode a LEDGF protein with the desired activity.

6. Claims 1, 8, 10, 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1, does not reasonably provide enablement for nucleic acid molecules which hybridize to SEQ ID NO:1 and encode a lens epithelial cell derived growth factor polypeptide, or for a nucleic acid molecule comprising deletions, additions and substitutions of nucleic acid molecules which hybridize to SEQ ID NO:1 and encode a respective lens epithelial cell derived growth factor polypeptide, or for a fragment of SEQ ID NO:13 without regard to the structure and/or function thereof, or for an agent that binds a nucleic acid molecule. Applicants' arguments have been fully considered but they are not persuasive. The hybridization language of the instant claims is analogous to the "sufficiently duplicative" language of Amgen's '008 patent claim 7, and, as indicated in the last Office action, the instant specification is even more limited than the '008 patent because it describes only a single protein and no analogs or mutants thereof and, therefore, provides even less support than the '008 specification for claims of comparable scope and which were held to be invalid in that patent.

7. Claims 1, 8, 10, 26 are rejected under 35 U.S.C. § 112, second paragraph, over the recitation of "stringent conditions" because stringency varies according to the hybridization conditions and the particular hybrid under study. Applicants' arguments have been fully considered but they are not persuasive. The specification at page 11, line 29, through page 12,

line 3, does not set forth a limiting definition of stringent conditions. The metes and bounds of the claim(s) are not clearly set forth.

8. Claim 26 is rejected under 35 U.S.C. § 112, second paragraph, over the recitation of "control" because the claim does not set forth that material element or combination of elements which is unique to, and, therefore, definitive of a "control" an artisan cannot determine what additional limitations are placed upon a claim by the presence of this term. Applicants' arguments have been fully considered but they are not persuasive. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

9. Claims 4-7, 9, 11 are rejected under 35 U.S.C. § 112, second paragraph, over the recitation of "identifying a nucleic acid molecule encoding a LEDGF" because the nature and extent of the "identification" are unclear. Applicants' arguments have been fully considered but they are not persuasive. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

10. The attempt to incorporate subject matter into this application by reference to GenBank accession numbers (Table III) is improper because the nucleotide sequences are critical or essential material to the practice of the invention.

The information disclosure statement filed 09/05/00 (Paper No. 13) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins, 486 F.2d 569, 179 USPQ

157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

11. Claims 4-7, 9-11 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Applicants' arguments have been fully considered but they are not persuasive. In those instances in which prior art sequences are only referred to in a given application by name and a publication or accession reference, they need not be included as part of the "Sequence Listing," unless an examiner considers the referred-to sequence to be "essential material," per MPEP § 608.01(p). See MPEP 2422.03. In the instant case the examiner considers the referred-to sequences to be "essential material". Applicant is required to amend the specification to include the sequences incorporated by reference because the sequences are essential material. Applicant must establish that the sequences added by amendment are the sequences present in the GenBank data base as of the filing date of the application. Applicant must establish that the inserted sequences were identical to those in the GenBank listings as of the filing date of the application. The public availability of GenBank sequences is acknowledged. However, the relevant issue is whether the inserted sequences were identical to those in the GenBank listings as of the filing date of the application.

12. Claims 4-7, 9-11 are rejected under 35 U.S.C. § 112, second paragraph, because they refer to GenBank accession numbers. The information disclosure statement filed 09/05/00 (Paper No. 13) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Furthermore, Applicant is required to amend the specification to include the sequences incorporated by reference because the sequences are essential material. The metes and bounds of the claim(s) are not clearly set forth.

New formal matters, objections, and/or rejections:

13. The information disclosure statement filed 09/05/00 (Paper No. 13) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of

any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Conclusion

14. Claims 2 and 3 are objected to as being dependent upon a rejected base claim.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

David Romeo
Primary Examiner
November 19, 2000